IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Palmaz, et al.	Attorney Docket:	6006-015
Serial No.:	09/707,685	Examiner:	Cheryl L. Miller
Filed:	11/07/2000	Art Unit:	3738
Conf No.:	9696	Customer No.:	29,335
Title:	ENDOLUMINAL STENT, SELF-SUPPORTING ENDOLUMINAL GRAFT AND METHODS OF MAKING SAME		

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APPELLANTS' REPLY BRIEF ON APPEAL

Dear Sir or Madam:

Appellants submit this Appellants' Reply Brief on Appeal in response to the Examiner's Answer mailed August 16, 2010 for the above-identified application. Appellants do not believe any additional fees are due in connection with the filing of this Reply Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

APPELLANTS' REPLY BRIEF ON APPEAL

1. Status of Claims

Claims 1-38 and 54-66 have been cancelled. Claims 39-53 and 67-74 are pending and stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0018381 to Whitcher et al. The rejection of claims 39-53 and 67-74 is under appeal.

2. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-53 and 67-74 are unpatentable under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0018381 to *Whitcher* et al. (hereinafter referred to as "*Whitcher*").

3. Argument

The Examiner's anticipation rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) over *Whitcher* is improper and should be withdrawn.

For a prior art reference to anticipate a claim, the prior art reference must teach every element of the claim. *See* MPEP §2131; *see also Richardson v. Suzuki Motor Co.,* 868 F.2d 1226. 1236 (Fed. Cir. 1989) (holding that "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." [Emphasis added].); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond,* 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation can not be established by mere equivalents).

The claimed invention is generally directed toward a method for manufacturing an endoluminal stent comprising, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material. The Examiner has failed to establish that *Whitcher* anticipates the claims on appeal because *Whitcher*

does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material. Applicants submit that independent claims 39, 47, and 67, and claims dependent therefrom, specifically dependent claims 40, 41, 42, 43, 44, 45, 46, 48, 49, 50, 51, 52, 53, 68, 69, 70, 71, 72, 73, and 74, are patentable over the prior art cited and of record.

a. *Any deposited amorphous or crystalline film in Whitcher does not mean or include minimized precipitates according to one of ordinary skill in the art*

The Examiner argues that *Whitcher* clearly discloses production of a crystalline structure. The Examiner alleges the following:

> Whitcher discloses that monocrystalline and nanocrystalline are examples of crystalline structures, see P0011 "have a crystallographic structure...include amorphous, nanocrystalline and monocrystalline", P0038 "the crystalline structure of the metallic medical article", P0040 "form the same crystalline structure, i.e. monocrystalline", P0043 "deposited material forms a crystalline structure", P0048 "formed to have a range of crystalline morphologies, including a monocrystalline or a nanocrystalline morphology."

Examiner's Answer dated August 16, 2010, p. 11-12. The amorphous film or a crystalline film, as disclosed by *Whitcher*, does not include or encompass minimized chemical and intra- and inter-granular precipitates. Additionally, the *Whitcher* reference does not define the term "precipitate" anywhere in the specification. Applicant sought to define "crystalline" (nanocrystalline and monocrystalline) in the Request for Continued Examination dated August 17, 2009, as to clearly distinguish "crystalline" from "precipitates" for the Examiner as one of ordinary skill in the art would interpret such terms and to clear any confusion the Examiner had with the two terms as understood by one of ordinary skill the art.

The term "monocrystalline" is undefined in *Whitcher*. However, "monocrystalline" is generally understood to mean "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit." (<www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm>, last accessed October 8, 2010, a copy which was previously submitted in Applicant's Request for Continued Examination dated September 1, 2009.) As is known by those skilled in the art, a single crystal results when the periodic and repeated arrangement of atoms is perfect or extends throughout the entirety of

the specimen without interruption. All unit cells interlock in the same way and have the same orientation. Single crystals thus have neither grains nor grain boundaries.

Whitcher discloses a method of making single crystals (monocrystals), wherein unwanted isotopes of the source material and impurities contained in the source material are filtered away before the material is deposited so that the lattice structure is not interrupted. Because the lattice structure of single crystals (monocrystals) is perfect, thereby having no grains or grain boundaries, atoms cannot be introduced which would interrupt it. Thus, *Whitcher* process conditions are selected to prevent the formation of grains. Applicant's process conditions are selected, however, to form grains and grain boundaries in the crystalline metal film, but also minimize formation of intra- or inter-granular precipitates within those grains. The Examiner's Answer belies these points and overlooks the crystal structure having grains (as the applicant has) and having no grains (as Whitcher has).

The term "nanocrystalline" is also undefined in *Whitcher*; however, it is generally understood to simply be nano-scale polycrystalline structures. (*See , e.g.*, Hollister, P., et al., Nanocrystalline Materials, Technology White Papers nr. 4, Cientifica, Oct. 2003, nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf, a copy of which was attached as Exhibit A to Appellant's Brief and previously submitted in Applicant's Request for Continued Examination dated August 17, 2009). The Applicant submitted Exhibit A in an effort to show and teach the Examiner about the concepts of monocrystalline and respectfully notes that Exhibit includes a publication date of October 2003, which is three years after the present application's filing date of November 7, 2000. Thus submission of Exhibit A under an IDS as noted by the Examiner is superfluous and unnecessary.

As widely known to those skilled in the metallurgical arts, the term "precipitate[1]", as it pertains to fabrication of biomaterials and with particular reference to nickel-titanium shape memory alloys, means reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, outside the metal crystalline structure. An excellent monograph on precipitation reactions in nickel-titanium binary shape memory alloy systems is found at Pelton, A.R., et al., Optimisation of processing and properties of medical grade Nitinol

[1] Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

Wire, *Min Invas Ther & Allied Techno.*, 2000: 9(1) 107–118, Published: 2001, a copy of which was previously submitted in Applicant's Request for Continued Examination dated September 1, 2009. Pelton is related to cold-work and heat treatment of nitinol and shows precipitates of nitinol that include $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. Pelton, p. 113.

Precipitates are formed during the increased thermal conditions of vacuum deposition techniques, i.e. heating a source material to a temperature to cause vaporization thereof for evaporization, or ionizing metals that collide with gas atoms and dislodge source material as in sputtering deposition, or using high energy beam of metals by ionizing a source material as in ion beam assisted deposition. For example, as is known in the art, the phase diagram for nitinol shows that at about 55.9 wt% Nickel, the precipitate $TiNi_3$ can form. As such, one of ordinary skill in the art would never equate monocrystalline with precipitates. Monocrystalline materials have no grains or grain boundaries, and thus, there are no grains in or between which precipitates may nucleate. One of ordinary skill in the art would also not equate nanocrystalline with precipitates, as precipitates themselves are outside the metal crystalline structure. The Examiner's confusion with these points supports the main rationale of the Examiner's anticipation argument.

Finally, *Whitcher* describes an amorphous film as the crystallization of structures formed with an amorphous morphology and an amorphous metallic structure may be deposited onto a substrate. Since the amorphous film is directed to the crystalline structure of the metallic film, it is not pertinent to or relevant to "precipitates," i.e. reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, outside the metal crystalline structure, such as $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. As such, any amorphous film in *Whitcher* does not include or encompass minimized chemical and intra and inter-granular precipitates.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

b. *Examiner cannot use the Applicant's own specification to support any anticipation or inherency argument, rationale, or fact*

The Examiner alleged the following with respect to process condition selected to minimize granular precipitates:

> [G]ranular precipitates are categorized in the applicant's specification as one of the many "material properties" that are collectively controlled by deposition, see

> pg. 10, lines 12- 16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg. 11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg. 11, lines 1 1-24) as the means for minimizing precipitates and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Examiner's Answer dated August 16, 2010, p. 5-6. The Examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. MPEP § 2129. It would not be appropriate for the Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. MPEP § 2144.03. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21, MPEP § 2144.03.

The applicants vehemently object to the Examiner using the applicants' own specification for any rationale and reasoning to support an anticipation or inherency argument for *Whitcher's* vacuum deposition processes selected to minimize the formation of intra and inter-granular precipitates. The Examiner's use of applicants' own specification is the best example of hindsight reasoning by the Examiner, and more importantly, nothing in the applicants' specification has identified the vacuum deposition steps selected minimize the formation of intra and inter-granular precipitates as prior art. The Applicant has made no admissions in the Applicant's specification, even though the Examiner chooses to characterize the Applicant's specification as so. The applicants respectfully request the Board to ignore the Examiner's use of the applicants' own specification to support the Examiner's §103(a) reasoning or official notice of such fact.

The Examiner's noticed fact of "collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process" is not considered to be common knowledge or well-known in the art. Moreover, any teaching of general vacuum

deposition in *Whitcher* is not enough for one of ordinary skill in the art, and specific parameters and vacuum deposition steps are disclosed in the applicants' specification to minimize the formation of precipitates, none of which are disclosed in *Whitcher*.

As the applicants will explain more fully below, the teachings in *Whitcher* do not minimize the formation of inter and intra-granular precipitates, and any inherency threshold cannot be overcome by using or relying on the teachings of applicants' disclosure for minimizing precipitates.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

c. *Whitcher* is not "inherently controlling and minimizing material properties such as granular precipitates just as much as applicants are."

As discussed above, the Examiner alleges in the Final Office Action and Examiner's Answer that "inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are." Examiner's Answer dated August 16, 2010, p. 5-6. The Examiner further states the following:

> "Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure. Further, process conditions are known in the art to comprise temperature, pressure, and deposition rate. Therefore, the user has completed the method under process conditions selected. What effect occurs (granular precipitates for instances) is inherently being controlled by the selection (that is whether there is little or a lot of precipitate changes depending on the users selection of the condition). "

Examiner's Answer dated August 16, 2010, p. 14-15. Contrary to the Examiner's contention, *Whitcher* does not teach "inherently controlling and minimizing material properties such as granular precipitates just as much as the applicants are."

First, applicants assert that any removal of impurities by *Whitcher* is for the purpose of filtering particular isotopes and not for the purpose of minimizing precipitates. As discussed above, *Whitcher* filters out unwanted isotopes and impurities to form a monocrystal (a/k/a single crystal), which has no grains or grain boundaries because its lattice structure is perfect and uninterrupted. *Whitcher* gives an example of titanium with an atomic weight of 48 that may be selected for vapor deposition, while rejecting titanium with atomic weights of 46, 47, 49, and 50,

or oxygen may be filtered away from the substrate. *Whitcher*, ¶ 0037. Such filtering methods for impurities in *Whitcher* is not for the purpose of, nor enables, the minimization of precipitates which are formed on the substrate as deposited metals, i.e. precipitates are formed during the increased thermal conditions of vacuum deposition techniques such as $Ti_{11}Ni_{14}$, Ti_2Ni_3, and $TiNi_3$. As such, any removal of impurities by *Whitcher* is for the purpose of filtering particular isotopes to form a monocrystalline material, which, unlike applicants' crystalline material, has no grains or grain boundaries, and thus has no precipitates that process conditions can be selected to minimize.

Applicants also assert that granular precipitates are not categorized as one of the many "materials properties" that are *collectively* controlled by deposition, as the Examiner contends. [Emphasis added]. With respect to the definition of "materials properties" applicants' specification recites:

> The term "material properties" is intended to encompass physical properties, including without limitation, elasticity, tensile strength, mechanical properties, hardness, bulk and/or surface grain size, grain composition, and grain boundary size, intra and inter-granular precipitates.

Present Application, p. 10, 11, 12-16.

The specification does not disclose that all of the listed properties are collectively controlled by deposition. Rather, as the applicants state in the specification, the "desired material properties" are controlled by vacuum deposition process conditions. *See* Specification at p. 11, Line 9. Applicants' listing of the physical properties that encompass "material properties" is simply a list of properties that may be controlled. All properties of a material are not cooperatively controlled or controlled as a group by deposition. For example, the process conditions selected to increase hardness are not the same process conditions selected to increase elasticity or the same process conditions selected to set a transition temperature. The Examiner's generalization of these points is inaccurate and inadmissible to support the anticipation rejection under *Whitcher*.

Moreover, applicants do not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties. First, if it was true that merely using vacuum deposition minimizes precipitates, then the annealing step in the prior art vacuum deposition processes would have been unnecessary, as that step was introduced in order to drive out the precipitates formed during deposition, which is the case for prior art vacuum deposition

processes. The applicants' specification states that its inventive process does not form precipitates and, hence, eliminates the need for a post-processing annealing step. Second, if it was true that the deposition process alone controlled the material properties, as the Examiner suggests, then all of the material properties would be *collectively* minimized or controlled simply by using the vacuum deposition process. As discussed above, this is untrue and flawed logic. Finally, applicants' vacuum deposition process conditions are selected to minimize (or substantially eliminate) the formation of granular precipitates. Applicants' inventive method does not merely reduce the size of precipitates (minimize precipitates) as suggested by the Examiner, rather the method prevents the formation of precipitates. The Examiner's focus on particular words and elements in the claim leads to an inaccurate claim construction and inappropriate anticipation rejection based on *Whitcher*. Thus, applicants' disclosure does not simply point to a vacuum deposition process as the means for minimizing precipitates and other material properties, but as stated in the applicants' Appeal Brief, the vacuum deposition processes incorporated by reference support the steps for preventing the formation of precipitates.

Further, the Examiner contends that because *Whitcher* discloses use of the same vacuum deposition process (sputtering, ion beam, etc.), use of the same materials, and that deposition processes control material properties, then *Whitcher* inherently controls granular precipitates. This reasoning is flawed. First, applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art. The Examiner has failed to provide any disclosure in *Whitcher* that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Second, as discussed above, the "material properties" are not collectively controlled by the deposition process. Finally, by way of analogy, the Examiner argues that to make a cookie, if one discloses use of the same cooking process (i.e. an oven, stove, microwave), use of the same ingredients, and that the cooking process controls cookie properties, then the resulting properties of the cookie are inherently controlled, for example, the softness or color of the cookie are inherently controlled. Any lay person reading this would recognize the severe flaw in logic. There are process conditions that would directly influence the resulting properties of the cookie such as the cooking time, temperature, placement in the oven (height and lateral distance from heat source), or the baking surface. *A change in any of these conditions could affect the resultant properties*.

Thus, using the same process and materials cannot render a property inherent, and more fully explained with respect to vacuum depositions below.

The '685 Board Decision stated that no working examples or specific vacuum deposition conditions are described in the Specification (FF8). The applicants previously indicated in the Request for Continued Examination filed August 17, 2009 that the present application states the following:

> As is described in co-pending, commonly assigned, U.S. Patent Application Serial No. 09/443,929, filed November 19, 1999, which is hereby incorporated by reference, heterogeneities are controlled by fabricating the bulk material of the stent to have defined grain sizes, chemical and intra and intergranular precipitates and where the bulk and surface morphology differ, yielding areas or sites along the surface of the stent while maintaining acceptable or optimal protein binding capability.

Present Application, p. 10, lines 24-30. So the present application indicates that chemical and intra- and intergranular precipitates are controlled by the vacuum deposition processes disclosed in U.S. Patent Application Serial No. 09/443,929. The present application also further states that when sputtering techniques are employed, a 200 micron thick stainless steel film may be deposited within about four hours of deposition time and it is preferable to employ a cylindrical sputtering target, a single circumferential source that concentrically surrounds the substrate that is held in a coaxial position within the source. Present Application, p. 11, lines 24-28. The U.S. Patent Application Serial No. 09/443,929 has subsequently issued as U.S. Patent No. 6,379,383 (the '383 patent") and the '383 patent discloses several working examples of sputtering a stainless steel film with a circumferential deposition source, whereby specific vacuum deposition conditions control the surface properties of the deposited metal film characterized by controlled heterogeneities in grain size, material composition and surface topography. See e.g. Examples 1-4 of the '383 patent. Applicants are not going against the '685 Board Decision, but simply pointed to additional supporting facts and evidence for the specific vacuum deposition conditions at which the applicants' invention is based on.

Such vacuum deposition conditions disclosed in the '383 patent are remarkably different than *Whitcher*, which include the following—the ceramic substrate has capabilities of glow discharge cleaning, pre-cleaning the substrates under vacuum by glow discharge, the substrate temperature between about 300 and 110 degrees and bias voltage between -1000 and +1000 volts for sputtering, deposition sources are circumferential and oriented to deposited from the target

circumferentially about the substrate. The '383 patent, col. 7, lines 8-22. *Whitcher* does not teach or disclose such vacuum deposition conditions and the Examiner inappropriately ignores these specific vacuum deposition process parameters and steps in any comparison with *Whitcher* for teaching or enabling the vacuum deposition conditions selected to minimize the formation of chemical and intra- and inter-granular precipitates in the bulk material. As such, the present application supports vacuum deposition conditions to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as deposited crystalline film, and *Whitcher* fails to anticipate such limitations in claims 39-53 and 67-74.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

d. *Whitcher* does not disclose *accurately and precisely controlling* the formation of granular precipitates.

According to the Examiner in the Examiner's Answer mailed on August 16, 2010, the Examiner alleges:

> Further, Whitcher specifically discloses accurately and precisely controlling the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Examiner's Answer mailed on August 16, 2010, p. 6. Contrary to the Examiner's contention, *Whitcher* does not "*accurately and precisely*" control the formation of granular precipitates. A review of the paragraphs cited by the Examiner reveals that they fail to support the Examiners' conclusions.

The Examiner cites paragraph 0038 of *Whitcher* to support the argument that granular precipitates are accurately and precisely controlled in *Whitcher*. In paragraphs 0037 and 0038, *Whitcher* teaches removing impurities from the metal material. Paragraph 0038 of *Whitcher* states, in relevant part, "[t]he removal of impurities and the filtering of particular isotopes are useful in the present invention." Applicants assert that removing impurities as taught by *Whitcher is not the same* as preventing the formation of precipitates as claimed by applicants. [Emphasis added]. Most familiar metals are alloys, in which impurity atoms have been added intentionally to impart specific characteristics to the material. The addition of impurity atoms to

a metal will result in the formation of a solid solution. A solid solution consists of atoms of at least two different types; the solute atoms occupying either substitutional or interstitial positions in the solvent lattice; and the crystal structure of the solvent is maintained. The reaction products formed from a solid solution under increased thermal conditions in vacuum deposition are precipitates; they are driven from the solid solution resulting in the formation of the reaction products outside the solid solution, i.e. the metal crystalline structure.

Moreover, *Whitcher* filters out unwanted isotopes and impurities to form a monocrystal (a/k/a single crystal), which has no grains or grain boundaries because its lattice structure is perfect and uninterrupted as in a monocrystal. Any removal of impurities by *Whitcher* is for the purpose of filtering particular isotopes to form a monocrystalline material, which, unlike applicants' crystalline material, has no grains or grain boundaries, and thus has no precipitates that process conditions can be selected to minimize. Thus, the difference between removing impurities as taught by *Whitcher* and preventing the formation of precipitates as claimed by applicants is blatantly clear with respect to metal alloys.

The Examiner also cites paragraphs 0042 and 0043 of *Whitcher* to support the argument that granular precipitates are accurately and precisely controlled in *Whitcher*. Paragraph 0043 makes clear that "[s]uch nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques (annealing) can be used to form nanometer sized crystals." It is manifestly and unequivocally clear that *Whitcher* teaches depositing a material onto a substrate in its amorphous state and after deposition treating or aging the amorphous structure (as expressly taught in paragraph 0041) to form either a nanocrystalline structure. This is, without question, different and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation.

In addition, the Examiner relies on Paragraph 0028 of *Whitcher* that states, in relevant part, that "[b]y using vapor deposition techniques for the formation of medical devices, the composition, thickness, surface roughness, and microstructures of devices formed in accordance with the present invention are accurately and precisely controlled." [Emphasis added]. It is clear from the Examiner's cited paragraphs that the devices formed in accordance with *Whitcher's* invention are formed from either (1) single crystal or monocrystalline materials or (2) nanocrystalline materials made by annealing an amorphous layer.

In paragraphs 0038, 0039, and 0040, *Whitcher* discloses forming medical devices made of single crystal or monocrystalline materials or forming a single crystal filament that is used as a substrate in a vapor deposition process to make a monocrystalline medical article. A single crystal results when the periodic and repeated arrangement of atoms is perfect or extends throughout the entirety of the specimen without interruption. Thus, a single crystal or monocrystalline material is one in which the arrangement of atoms is perfect or extends throughout the entirety of the specimen without interruption, and has no grains or grain boundaries.

In the aforementioned paragraphs, *Whitcher* only discloses forming medical devices from single crystal or monocrystalline materials. Paragraphs 0042 and 0043 both refer to medical devices made of nanocrystalline materials that were made by annealing an amorphous layer. *Whitcher* therefore discloses accurately and precisely controlling the microstructures of the devices made from either (1) single crystal or monocrystalline materials that have no grains or grain boundaries or (2) nanocrystalline materials made by annealing an amorphous layer. Applicants' devices, however, are not fabricated from the aforementioned materials, thus *Whitcher* does not teach accurately and precisely controlling their microstructures as contended by the Examiner.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

e. *Whitcher's selection of a process condition does not inherently minimize precipitates.*

According to the Examiner in the Final Office Action and Examiner's Answer, the Examiner alleges:

> Additionally, Whitcher discloses selection of a process condition. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has controlled the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the selection. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Examiner's Answer mailed on August 16, 2010, p. 9.

Applicants submit that it is not sufficient for the Examiner to base an anticipation rejection relying on inherency on broad generalizations regarding the prior art.

> "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

See MPEP §2112.

The Examiner has failed to provide any disclosure in *Whitcher* that clearly and specifically provides the elements of the claims on appeal, either expressly or inherently. Applicants respectfully assert that *Whitcher* merely states conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, none of the Examples found in *Whitcher* contain any statement or suggestion that the vacuum deposited film is crystalline, or that precipitate formation is, in fact, controlled. The inherency standard and threshold has not been established by a remote possibility. Moreover, applicants submit that the Examiner has not explained, by presenting a preponderance of evidence, or any evidence, why a person of ordinary skill in the art would recognize that the allegedly inherent characteristic necessarily flows from the teachings of *Whitcher*. To the extent that the Examiner's opinion is based on her personal knowledge, applicant requests under 37 C.F.R. §1.104(d)(2) that Examiner provide such information specifically and with support by a reference, all presented by affidavit of the Examiner.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

f. *Process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague and arbitrary and the Examiner has not properly considered the limitation.*

According to the Examiner in the Final Office Action and Examiner's Answer, the Examiner alleges:

> [A]pplicant has claimed "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition.

Examiner's Answer mailed on August 16, 2010, p. 7. The Examiner complains that "minimize" is vague and arbitrary; however, the Examiner has not rejected Claim 39 on any basis under 35 U.S.C. §112, second paragraph for indefiniteness. More so, a claim limitation which is considered definite cannot be disregarded, a canon that the Examiner conveniently ignores. MPEP § 2143.03.

Again, the reaction products formed from a solid solution under increased thermal conditions of vacuum deposition are precipitates; they are driven from the solid solution resulting in the formation of the reaction products outside the solid solution, i.e. the metal crystalline structure. Minimizing the formation of precipitates in a metal alloy minimizes the solid solution reaction products forming under increased thermal conditions during vacuum deposition. "Minimize" generally means "reduce or keep to a minimum." (www.merriam-webster.com, last accessed October 8, 2010.) Thus, the claim term "minimize intra- and inter-granular precipitates" would generally mean reduce or keep the precipitates to a minimum.

The Examiner's confusion of "minimize" belies the Examiner's point that *Whitcher's* vacuum deposition process is selected to minimize formation of chemical and intra and inter-granular precipitates, as the Examiner has not properly construed the limitation "process conditions selected to minimize formation of chemical and intra and inter-granular precipitates;" thus how can the Examiner properly conclude that *Whitcher* selects any vacuum deposition process conditions to minimize the formation of precipitates. Therefore, the process conditions selected to minimize formation of chemical and intra and inter-granular precipitates is not vague

and arbitrary, and the Examiner has not properly considered the "vacuum deposition process is selected to minimize formation of chemical and intra and inter-granular precipitates", and *Whitcher* fails to anticipate the limitation according to the Examiner's rationale. The Examiner's misconstruction of Claim 19 leads the Examiner down an erroneous rationale to reject the claim based on anticipation, inherently or not.

For at least these reasons, applicants submit that pending claims 39-53 and 67-74 are distinguished from and patentable over the prior art cited and of record.

Conclusion

An anticipation rejection under 35 U.S.C. §102(e) requires that the cited prior art reference must disclose each and every claimed element. *Whitcher* does not teach or suggest every limitation recited in the pending claims on appeal. More specifically, *Whitcher* fails to teach a method of manufacturing an endoluminal stent comprising the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical or intra- and inter-granular precipitates in the bulk material. Furthermore, *Whitcher* does not enable the teaching for which the Examiner relies on *Whitcher*. Thus, *Whitcher* does not anticipate the pending claims on appeal, and the Examiner's anticipation rejection is improper and should be withdrawn.

Accordingly, applicants respectfully request that the Board withdraw the 35 U.S.C. §102(e) rejection of claims 39-53 and 67-74, and allow the above-identified application to proceed to allowance and issuance.

Respectfully submitted,

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October 14, 2010

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